DECLARATION UNDER 37 C.F.R. § 1.132		
	Application #	10/693,955
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	First Inventor	LAURIE
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	Examiner	Sheikh, Humera N.
	Docket #	P07351US01/BAS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

S I R:

I, William Alfred Smith, declare that:

1. I am the Technical Manager of the applicant of the above-identified U.S. patent application. I have been involved in all stages of the development of the patent application. I am aware of the currently pending claims and have reviewed the outstanding Office Action issued by the U.S. Patent Office on March 4, 2009.

2. As I understand, in the outstanding Office Action, claims 11, 12, 14 and 16 were rejected as being obvious in view of U.S. Patent No. 4,335,116 (hereinafter "Howard").

3. Claim 11 is directed to an injectable trace element solution comprising trace elements zinc, manganese, selenium and copper. The solution has a metal concentration of trace elements of 60 mg/ml.

4. Howard discloses water soluble organometallic complexes of ions of zinc, copper, magnesium, chromium and selenium. Further, Howard discloses a number of

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specific solutions, including those in Examples 1 and 2. In Example 1, the aqueous solution contains, per milliliter, 4.0 mg zinc ion, 1.0 mg copper ion, 3.0 mg manganese ion, 0.5 mg chromium ion and 5.0 mg selenium ion, for a total trace element concentration of 13.5 mg/ml. In Example 2, Howard discloses an aqueous solution containing, per milliliter, about 0.83 mg zinc ion, 0.17 mg copper ion, 0.67 mg manganese ion, 0.03 mg chromium ion, 0.67 mg selenium ion, 33 mg iron ion and 0.005 mg cobalt ion. Thus, the trace element concentration is 2.38, with a total metal concentration, i.e. including iron, of 35.38 mg/ml.

5. Howard does allege that its invention may include a solution which allows each milliliter thereof to contain from about 0.1 to about 25 mg of zinc, from about 0.1 to about 10 mg of copper, from about 0.1 to about 20 mg of manganese, from about 0.01 to about 5 mg of chromium and from about 0.1 to about 12 mg of selenium (see, e.g., Howard, column 5, lines 28-35 and Howard, claim 1).

6. Although Howard alleges that its solution may have the ranges described above in paragraph 5, the method described in Howard for producing its trace element solution would not allow one of ordinary skill in the art to produce a trace element solution having anywhere near 60 mg/ml of trace elements in solution. Although the total milligrams per milliliter of trace elements would be 72 mg/ml if one were to add up the upper limits of the ranges listed above in paragraph 5, none of the actual examples disclosed in Howard have anywhere near 72 mg/ml. To the contrary, in Example 1, the metal concentration is 13.5 mg/ml and Example 2 has a trace element concentration of

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2.38 mg/ml (i.e. the zinc, copper, manganese, chromium, selenium and cobalt ion amounts), and the total metal concentration is 35.38 mg/ml.

7. Moreover, the method disclosed in Howard would not permit one of ordinary skill in the art to produce a 60 mg/ml trace element solution. As an initial point, as far as the present inventors are aware, despite the fact that the Howard patent issued in 1982, no product has been manufactured by its method or distributed anywhere in the marketplace. In contrast, since the filing of the present application, multiple millions of doses have been sold in the U.S. This is due to the fact that the method of Howard cannot produce a product that improves the trace mineral status of an animal, particularly due to the low trace mineral concentration resulting from dilution. For example, in Example 1 of Howard, the solution only achieves a mineral concentration of 13.5 mg/ml, whereas, in the present invention, a solution achieves a mineral concentration upwards of 100 mg/ml. Example 6 of the present invention discloses a mineral concentration of 60 mg/ml. As a result, the present invention results in a trace element concentration which is at least 4.5 times greater than that which is disclosed by any actual example in Howard (when comparing the present 60 mg/ml solution of the present Example 6 to the 13.5 mg/ml solution disclosed in Howard [maximum concentration disclosed in Howard, Example 1]).

8. The present invention is capable of producing a product with concentrations as claimed due, in part, to the use of continuous process, as compared with Howard's single process approach, and the relative stabilities of the minerals to be included. In

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simple terms, in 10 ml of a liquid it may be possible to simultaneously dissolve 10 mg of mineral B and 10 mg of mineral C, to obtain a 10 ml solution containing 10 mg of B and 10 mg of C. However, in accordance with Howard, 2 separate solutions are used to dissolve the 10 mg of B and 10 mg of C. The separate solutions are combined to produce a 20 ml solution containing 10 mg of B and 10 mg of C, or only 5 mg B and 5 mg C/10 ml of solution.

9. A further distinction which allows the present method to produce the claimed concentration, which is absent from Howard, is that the present invention uses EDTA and/or disodium EDTA, whereas Howard uses tetrasodium EDTA. The variants used, according to the present method, have a higher complexing power than tetrasodium EDTA, namely EDTA's acid has a calcium complexing power of 335 mg/g and disodium EDTA has a calcium complexing power of 266 mg/g, whereas tetrasodium EDTA only has a calcium complexing power of 220 mg/g.

10. In conclusion, although Howard may, *arguendo*, allude to being able to produce a trace element solution having a total trace element mineral concentration of 72 mg/ml, if one were to consider the upper limits of the ranges of its trace elements, the method disclosed in Howard, and any method known in the art at the time of Howard, fails to provide a method which would allow one of ordinary skill in the art to produce such a solution with a 72 mg/ml concentration. Moreover, no method before the present method would permit one to produce a solution having a concentration of trace elements comprising 60 mg/ml.

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11. The undersigned declares further that all statements made herein of his knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 26TH day of AUGUST 2009.

/WaSmith/

William Alfred Smith